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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,853	10/17/2007	Katsumi Aoyagi	053466-416	4864

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,853	AOYAGI ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-14,16-21 and 24-29* is/are pending in the application.

4a) Of the above claim(s) *2,8-14,16-21 and 24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note that this application has been transferred to another Examiner and all future correspondences should be directed to Michelle Horning of AU 1648.

This action is responsive to communication filed 6/22/2010.

Claims 1 and 4-7 are under current examination.

Any rejection(s) and/ or objection(s) not reiterated herein have been withdrawn.

Election/Restrictions

Claims 2, 8-21 and 24-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

With respect to the withdrawal of claims 2 and 3, applicant submits that the fact that a claim may also require additional elements is not a basis for its withdrawal from consideration, and the Office does not cite support for this practice. Applicant seeks the rejoinder and examination of claim 2 and its dependent claim.

In response, note that the Requirement for Restriction/Election mailed out 10/9/2009 required the election of *one or a combination* of a protein denaturing agent, an amphoteric surfactant, a cationic surfactant, a monosaccharide or disaccharide, a citric acid, a non-ionic surfactant and a reducing agent following the election of group I. Applicant was also required to elect on of the acidifying agent of claims 5 or 16.

Applicant elected HCl and a combination of amphoteric surfactant with a cationic surfactant; see p. 1 of Applicant's Remarks filed 11/6/2009.

Because the withdrawn claims require additional elements to the elected combination (e.g. a monosacaccharide or a disaccharide; see claim 2) that was not elected by Applicant, this restriction is both proper and final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Aoyagi et al. (WO 00/07023-teachings referenced as translated in US 7316905, referred to by Applicant as "Aoyagi III"), Aoyagi et al. (Aoyagi II, WO 99/06836 or EP0967484). These claims are drawn to methods of treating HCV containing samples with an acidifying agent (such as hydrochloric acid) and with an amphoteric or cationic surfactant having both a straight (linear) alkyl group

of 10 or more carbon atoms and a tertiary or quaternary ammonium salt (amine). Claims 6 and 7 identify, respectively, potential amphoteric and cationic surfactants according to claim 1 that may be used to treat the sample.

Aoyagi teaches a method for the detection of HCV antigens in a sample comprising introducing the sample into conditions that comprise one or more detergents, preferable comprising a linear alkyl chain with 10 or more carbon atoms, and preferable containing a tertiary or quaternary amine; and using an antibody to the antigen to detect the presence of the antigen. Columns 6-7, esp. col 7 lines 25-48. The reference provides examples of both cationic and amphoteric detergents that may be used in such methods in lines 39-48 of column 7, which examples include or render obvious several of those presented in present claims 6 and 7. The reference teaches that these detergents are used for the purpose of efficiently detecting antigen in HCV particles without applying pre-processing including centrifugation (col. 7, lines17+). However, the reference does not teach or suggest the pre-treatment of the samples with an acidifying agent.

Like Aoyagi, the Aoyagi II reference also teaches methods for improving the sensitivity of an assay for HCV antigens. See e.g., abstract, and pages 23-26 of application 09/269897 (representing a translation of relevant portions of the Aoyagi II reference- attached as an appendix to the present application). This reference teaches the pretreatment of samples with a combination of an acidifying agent such as hydrochloric acid, a surfactant, and an additional agent. See e.g., translation as found on page 25. Among the surfactants identified as useful in the acid treatment step is the

amphoteric surfactant dodcyldimethylammino propanesulfante. Pages 25-26. This surfactant is also among those disclosed in claim 6, and those identified in the Aoyagi reference (column 7, lines 34-48) as useful for the same purpose as in the Aoyagi II reference.

In view of the above, it would have been obvious to those of ordinary skill in the art to combine the steps of treating the samples with the acidifying agent and surfactants of Aoyagi II with the treatment of the samples with the detergents of Aoyagi for the purpose of reducing the number of agents required, and the number of steps being used to treat the samples. I.e., it would have been obvious to those of ordinary skill in the art to pre-treat the samples with all of the acidifying agent, surfactant, and additional agent of Aoyagi II, using the amphoteric surfactants of Aoyagi as the surfactant. Because Aoyagi indicates that the detergents may be combined to provide synergistic results, it would have been obvious to those of ordinary skill in the art to use the amphoteric surfactant either alone or in combination with a cationic surfactant of Aoyagi.

Thus, the presently claimed methods would have been obvious to those of ordinary skill in the art based on the combination of the teachings of these references.

Response to Arguments

Applicant's arguments filed 6/22/2010 have been fully considered but they are not persuasive. The arguments are addressed as they are presented in the Remarks.

Applicant acknowledges that Aoyagi III (US Patent 7316915) describes the use of an acidic agent but submits that this reference does not teach a method which uses an acidic agent with an amphoteric surfactant.

Applicant further contends that Aoyagi II (WO 99/06836 or EP0967484) does not teach or suggest a method that uses an acidic agent with an amphoteric surfactant or a cationic surfactant.

In response, the references do teach a combination of acidic agent and surfactant; see claim 8 of the EP '484 reference. While the claim teaches using "nonionic" surfactants, the reference as a whole clearly teaches the equivalency of nonionic surfactants to amphoteric surfactants; see claim 1 of this reference.

Applicant submits that this rejection relies on an "obvious to try" rationale. However, this is not relevant because the rejection was not based upon such but on the clear teachings of the references. The prior art as a whole clearly provided reasons to combine an acidifying agent and either an amphoteric or cationic surfactant. This is clearly seen in claim 8 of the EP ‘484 reference as well as the entire document. Both the surfactant and acidifying agent are taught to have a clear purpose in treating a sample with HCV. For example, [0079] teaches the use of acid treatment in inactivating antibodies. The use of the surfactants is shown to clearly increase reactivity in an HCV sample; see [0167] and Table 10, disclosing the results of treatment with either an amphoteric or cationic surfactant. The cited references teach that combining an acidifying agent and various surfactants, including those claimed, provide the advantage

of improving the sensitivity of an assay for HCV antigens well reducing the number of steps in the treating the samples.

Applicant contends that the claimed inventions shows unexpected results and cites Example 8 of the instant specification.

In response, this is not found persuasive for the following reasons:

First, the comparison in Example 8 is not a comparison with the closest prior art. It fails to show a comparison with the specific individual acidifying agents and surfactants alone as compared to the combinations of acidifying agents and surfactants of the instant invention. Second, the data in Example 8 is not commensurate in scope with the claimed invention. Note that Example 8 uses a composition of specific acidifying agent, surfactant etc. while the claims are broad to various acidifying agents and surfactants. A single data point, such as shown in Example 8, does not provide the requisite showing that a trend would hold true over the scope of the claims. Last, the results shown do not appear to be unexpected but appear to be the expected result of using a combination of acidifying agent and surfactant, both taught by the references. There is no showing that the alleged unexpected result is any more than additive effect.

Conclusion

No claim is allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648